

Appln No. 10/758,915

Amtd date June 27, 2005

Reply to Office action of March 28, 2005

REMARKS/ARGUMENTS

Claims 1-34 are currently pending in the application.

Reconsideration is respectfully requested.

I. Rejection Under 35 U.S.C. § 112

First § 112 Rejection

On page two of the Office action, the Examiner rejected claims 13-15 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter Applicant regards as the invention. The Examiner based the first § 112 rejection on his statement that claims 13-15 are unclear because they do not include the basis for the percentage measurement e.g. by weight, volume, mole, etc.

Applicant has amended the claims to recite that the measurement percentages are by weight. Support for the Amendment is provided in the application pages 6-14 where the percentages of the bleaching gel ingredients are listed on a weight/weight basis.

Second § 112 Rejection

Claims 13-15 were rejected under 35 U.S.C. § 112 as containing various trademark names. Applicant has amended the claims to recite the generic names of the trademark components. For example, Klucel GF has been replaced by hydroxypropyl cellulose; CAB-0-SIL EH-5 has been replaced by fumed silica; Polawax NF has been replaced by emulsifying wax. The trademarked materials are identified in the application

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specification with their generic names at pages 4 ((CAB-0-SIL as Fumed Silica), (Klucel GF as Hydroxypropyl Cellulose) and (Polawax as a Emulsifying Wax)).

II. Rejection Under 35 U.S.C. §102 (e) - Claim 16

On page 3 of the Office Action claim 16 is rejected under 35 U.S.C. §102(e) as anticipated by Chadwick et al. (U.S. Patent No. 6,555,020).

The Examiner based his rejection on his statement that "Claim 1 of the prior art recites an aqueous dental bleaching gel comprising "at least one bleaching agent selected from the group consisting of hydrogen peroxide and compounds that release hydrogen peroxide."

The Examiner went on to state that the specification only discloses one example of compounds that release hydrogen peroxide, namely carbamide peroxide (col. 4, lines 39-46) and "that species is specifically recited in claim 2 of the that patent as well." The Examiner goes on to state that this "effectively means that claim 1 encompasses only three possible bleaching agents: 1) hydrogen peroxide, 2) carbamide peroxide, and 3) a mixture of hydrogen peroxide and carbamide peroxide. The Examiner continues that "a selection need only be made from a very limited group, since the phrase "at least one" is tantamount to a discrete disclosure of a mixture, and since the only choice for the additional agent in the mixture is carbamide peroxide, the prior art appears to be sufficiently specific to be anticipatory of instant claim 16. (Insofar as the Examiner can determine, the prior art does not disclose incorporating a radiant energy or heat energy activator substance.)

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This rejection is respectfully traversed.

Claim 16 has been amended to define a two component bleaching system comprising a dual barrel syringe wherein the first barrel contains a bleaching gel composition comprising carbamide peroxide and aqueous hydrogen peroxide in the absence of a radiant energy or heat energy activator substance and the second barrel contains an orally compatible activator gel.

Applicant submits that claim 16 as amended is clearly not anticipated by Chadwick et al (U.S. Patent No. 6,555,020). The Chadwick et al. reference discloses a one component system which includes a bleaching gel deliverable from a single barrel syringe or other single barrel device and does not disclose a two component system comprising a dual barrel syringe as defined by claim 16.

In view of the foregoing, Applicant submits that claim 16 is not anticipated by the disclosure of the Chadwick et al. reference and, thus respectfully requests allowance of claim 16.

III. Rejection under 35 U.S.C. §103(a)

On page 4 of the Office Action, claims 1-10 and 25-32 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,116,900 (Ostler) (primary reference) in view of U.S. Patent No. 5,858,332 (Jensen et al.) (secondary reference).

Examiner Statement of Rejection

(1) The Examiner noted that the primary reference (the '900 Ostler patent) discloses a two-chambered syringe for tooth whitening, where the first chamber contains peroxide, and the second contains a basic element (col. 3, lines 47-53). The basic element contains a basic compound such as sodium hydroxide

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to increase its pH (col. 5, lines 19-27). The peroxide and basic element are admixed prior to application (col. 3, lines 54-57), and thus are "adapted to be admixed and applied to the teeth from a dental tray for sustained contact" as required by the instant preamble. The compositions of the primary reference are preferably provided in gel form: see col. 5, lines 55-60. When used by the patient, the components of the first and second chambers are dispensed from the syringe into a bleaching tray while mixing the components together to form an active bleaching gel, just as is done in instant claims 25-32. See col. 8, lines 36-49.

(2) The primary reference differs from the instant claims insofar as it does not specifically disclose a mixture of hydrogen peroxide and carbamide peroxide, instead teaching the use of each singly, with hydrogen peroxide being preferred. (Col. 5, lines 50-54).

(3) The secondary reference (the '332 Jensen et al. patent) teaches that where it is known to use carbamide peroxide and hydrogen peroxide individually as active agents in a particular bleaching gel, it is further known to use mixtures of the two in varying concentrations to provide "bleaching compositions having a wide spectrum of bleaching agent concentrations" (col. 5, lines 59-63), i.e., a varied spectrum of bleaching activity (with carbamide peroxide acting more slowly than hydrogen peroxide). The secondary reference differs from the instant claims insofar as it is limited to one-component systems, rather than two-component systems as required instantly.

(4) It would have been obvious to have combined the individually disclosed hydrogen and carbamide peroxides of the

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primary reference bleaching gels in varying concentrations, motivated by the desire to provide bleaching compositions having a wide spectrum of bleaching activities, as taught by the secondary reference.

(5) Regarding dependent claims 3-10, it is well-settled that normally, changes in result effective variables are not patentable where the difference involved is one of degree, not kind; experimentation to find workable conditions generally involves the application of no more than routine skill. See *In re Aller* 105 USPO 233, 235 (CCPA 1955). Similarly, the determination of optimal values is generally considered obvious. *In re Boesch* 205 USPQ 215 (CCPA 1980). See also *In re Peterson* 315 F.3d 1325 (C.A. Fed. 2003). (That court reaffirming the previous *Aller* and *Boesch* decisions, stating at page 1330 that: "the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a set of disclosed percentage ranges is the optimum combination of percentages.") Accordingly, it would have been obvious to one skilled in the art, having arrived at the subject matter of instant claim 1, to have routinely tested various relative concentrations of carbamide and hydrogen peroxide to determine workable/optimal values, consonant with the reasoning of the above-cited precedent.

(6) Regarding dependent claim 2, the primary reference teaches the use of the gelling agent hydroxyethyl cellulose (col. 5, line 57), rather than hydroxypropyl cellulose. It is well-settled, however, that a *prima facie* case of obviousness may be based upon structural similarity, i.e., an established structural relationship between a prior art compound and a

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claimed compound, such as homology or position isomerization. See *In re Deuel* 51 F.2d 1532, 1559 (Fed. Cir. 1995); the necessary motivation to make the claimed compound, and thus the prima facie case of obviousness, arises from the reasonable expectation that compounds similar in structure will have similar properties. See *In re Grabiak* 769 F.2d 729, 733 (1985); see also *In re Gvurik* 596 F.2d 1012 (CCPA 1979). Accordingly, it would have been obvious to have used hydroxypropyl cellulose in place of hydroxyethyl cellulose as the gelling agent of the primary reference compositions, motivated by the reasonable expectation that two compounds, which are similar in structure (related essentially as homologues), would have correspondingly similar gelling properties, consonant with the reasoning of the cited precedent.

The rejection of claims 1-10 and 25-32 is respectfully traversed.

The Examiner admits that the primary reference does not disclose a mixture of hydrogen peroxide and carbamide peroxide. Applicant submits that the primary reference also does not provide any motivation for one of skill in the art to use a mixture of hydrogen peroxide and carbamide peroxide in a two-component dental bleaching system. While the secondary reference mentions that hydrogen peroxide solutions and carbamide peroxide solutions can be mixed together in varying concentrations, it is mainly concerned again with a one-component composition having

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sufficient shelf life, and not a two-component composition or system. See col. 3, lines 34-40. In addition, the secondary reference also teaches that the "type and amount of hydrogen peroxide to be used will depend on the desired peroxide concentration in the final dental bleaching composition. In general, it will be preferable to use concentrated hydrogen peroxide solutions when it is desired to manufacture a bleaching composition having high concentrations of bleaching agent. Lower concentrated hydrogen peroxide solutions and/or carbamide peroxide and/or sodium perborate are generally used when it is desired to manufacture a bleaching composition having lower concentrations of bleaching agent." See col. 5, lines 49-59. The reference then goes on to disclose examples where only hydrogen peroxide alone is used at levels of between 3.5 and 90%. See col. 9, line 51 to col. 12, line 18.

Independent Claims 1 and 25 are Not Obvious Under § 103

Independent claim 1 of the present application defines a two-component dental bleaching system comprising a first component comprising both carbamide peroxide and hydrogen peroxide. Independent claim 25 defines a method for bleaching teeth by providing a dual barreled syringe wherein the first barrel is loaded with a dental peroxide gel comprising both

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carbamide peroxide and hydrogen peroxide and the second barrel is loaded with an orally compatible activator gel.

Three criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference, or combination of references, must teach or suggest all the claim limitations. MPEP § 2142. Applicant respectfully submits that there is no suggestion or motivation in the primary reference to combine its teaching of a two component system with that of a one-component system to arrive at a two component system of claims 1 and 25 of the present invention. In addition, applicant submits that the secondary reference teaches away from such combination when it teaches that "it will be preferable to use concentrated hydrogen peroxide solutions when it is desired to manufacture a bleaching composition having high concentrations of bleaching agent" (col. 5, lines 52-55). Therefore, applicant submits that independent claims 1 and 25 are patentable over Ostler (USP 6,116,900) in view of Jensen et al (USP 5,858,332).

Dependent claims 2-10, which depend from independent claim 1, and claims 26-32, which depend from independent claim 25 were also rejected under 35 U.S.C. §103(a) as being unpatentable over

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Ostler (USP 6,116,900) in view of Jensen et al (USP 5,858,332). While Applicants do not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are moot in view of the remarks made in connection with independent claims 1 and 25. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 2-10 and 26-32 are also in condition for allowance.

Applicant respectfully request that the rejection of claims 1-10 and 26-32 under 35 U.S.C. § 103(a) as being unpatentable over Ostler (USP 6,116,900) in view of Jensen et al (USP 5,858,332) be withdrawn.

Claims 11, 12, 33 and 34 are Rejected Under 35 U.S.C. 103(a) as Being Unpatentable Over U.S. Patent No. 6,116,900 (Ostler) in View of U.S. Patent No. 5,858,332 (Jensen et al.) in Combination Further of U.S. Patent No. 5,486,350 (Norfleet et al.)

The Examiner indicated (1) that the primary and secondary references, and the rationale for combining their teachings are discussed in detail in subsection 1 of the Office Action above and (2) that the subject matter fairly suggested by their combined teachings differs from the instant claims insofar as the incorporation of sodium fluoride and potassium nitrate

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(claims 11 and 33), or potassium nitrate and tetrapotassium pyrophosphate (claims 12 and 34) is not specified.

The Examiner goes on to state that (1) "the tertiary reference (U.S. Patent No. 5,486,350 - Norfleet) teaches that it is well-known to incorporate these additional ingredients into dentrifices. Specifically, mixtures of potassium nitrate and tetrapotassium pyrophosphate are used to reduce tooth sensitivity (col. 1, lines 9-18, for example), with sodium fluoride being used to stabilize the pyrophosphate (col.4, lines 37-49); (2) the tertiary reference differs from the instant claims insofar as it does not specifically disclose bleaching gels (a type of dentrifice); and (3) it would have been obvious to have added sodium fluoride, potassium nitrate and tetrapotassium pyrophosphate to the bleaching gels suggested by the combined teachings of the primary and secondary references, motivated by the desire to increase the comfort of patients having sensitive teeth while undergoing the bleaching procedure, since those compounds are known sensitivity reducers as taught by the tertiary reference.

Applicant respectfully traverses this rejection.

Applicant submits that the rejections of claims 11 and 12 which depend from claim 1 and claims 33 and 34 which depend from claim 15 are moot in view of the remarks made in connection with independent claims 1 and 25. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 11 and 12 and 33 and 34 are in condition for allowance.

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Applicant respectfully requests withdrawal of the rejection of claims 1, 11 and 12 and 25, 33 and 34 under 35 U.S.C. § 103(a) as being unpatentable over Ostler (USP 6,116,900) in view of Jensen et al (USP 5,858,332), the combination being taken further in view of Norfleet et. Al. (USP5,486,350).

Claim 17-24 Rejected Under 35 U.S.C. §103(a)

Claim 17-24 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,555,020 (Chadwick et al.) in view of U.S. Patent No. 5,858,332 (Jensen et al.).

The Examiner based his rejection of claims 17-24 on his statements that (1) the primary reference (Chadwick et al.) discloses aqueous dental gels comprising hydrogen peroxide or carbamide peroxide, the total amount of bleaching agent ranging from 3 to 50 percent by weight of the gel (col. 4, lines 33-46); (2) claim 1 recites the use of "at least one" bleaching agent, thus teaching the use of mixtures. Specific combinations, i.e. exemplified combinations with specified percentages of each agent, are not specified, however, as required by the instant claims; and (3) the secondary reference (Jensen et al.) teaches that where it is known to use carbamide peroxide and hydrogen peroxide individually as active agents in a particular bleaching

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gel, it is further known to use mixtures of the two in varying concentrations to provide "bleaching compositions having a wide spectrum of bleaching agent concentrations" (col. 5, lines 59-63), i.e., a varied spectrum of bleaching activity (with carbamide peroxide acting more slowly than hydrogen peroxide); (4) the secondary reference differs from the instant claims insofar as it is limited to one-component systems, rather than two-component systems as required instantly; and finally (4) that it would have been obvious to have combined the individually disclosed hydrogen and carbamide peroxides of the primary reference bleaching gels in varying concentrations, motivated by the desire to provide bleaching compositions having a wide spectrum of bleaching activities, as taught by the secondary reference.

Applicant respectfully traverses this rejection.

Claims 17-24 depend from claim 16 and thus, include all of the limitations of claim 16 as well as the specific limitations of each of the respective dependent claims.

Applicant submits that claims 17-24 are not obvious over Chadwick et al. in view of Jensen et al. for essentially the same reasons set forth above with respect to claim 16 not being anticipated by Chadwick et al. For example, the Chadwick et al. reference discloses a one component system which includes a bleaching gel deliverable from a single barrel syringe or other

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single barrel device and does not disclose a two component system comprising a dual barrel syringe as defined by claims 17-24 as amended.

Applicant respectfully submits that claims 17-24 are in condition for allowance and allowance is respectfully solicited.

Claim 16-24 are Rejected Under 35 U.S.C. § 103(a) as Being Unpatentable Over U.S. Patent No. 5,725,843 (Fisher) in View of U.S. Patent No. 5,858,332 (Jensen et al.)

The Examiner bases his rejection on his statements that (1) the primary reference discloses aqueous dental bleaching gels comprising a bleaching agent; (2) the reference clearly teaches that the "concentration of dental bleaching agent may vary depending on its reactivity," with either 3 to 20 percent by weight carbamide peroxide, or 2 to 10 percent by weight hydrogen peroxide being preferred. See col. 4, lines 54-63; (3) the primary reference differs from the instant claims, however, insofar as it is silent regarding mixtures of bleaching agents.; and (4) the secondary reference teaches that where it is known to use carbamide peroxide and hydrogen peroxide individually as active agents in a particular bleaching gel, it is further known to use mixtures of the two in varying concentrations to provide "bleaching compositions having a wide spectrum of bleaching agent concentrations" (col. 5, lines 59-63), i.e., a varied

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spectrum of bleaching activity (with carbamide peroxide acting more slowly than hydrogen peroxide). The secondary reference differs from the instant claims insofar as it is limited to one-component systems, rather than two-component systems as required instantly.

This rejection is respectfully traversed.

As was set forth above, claim 16 has been amended to define a two component bleaching system comprising a dual barrel syringe wherein the first barrel contains a bleaching gel composition comprising carbamide peroxide and aqueous hydrogen peroxide in the absence of a radiant energy or heat energy activator substance and the second barrel contains an orally compatible activator gel.

Applicant submits that independent claim 16 and claims 17-24 which depend therefrom are not unpatentable under 35 U.S.C. § 103 as obvious over U.S. Patent No. 5,725,843 Fisher in view of U.S. Patent No. 5,858,332 Jensen et al.

Both the Fisher patent and the Jensen et al. patent disclose one component systems which include a bleaching gel deliverable from a single barrel syringe or other single barrel device and do not disclose or suggest a two component system

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comprising a dual barrel syringe as defined by claim 16 and claims 17-24 which depend therefrom.


In view of the foregoing, Applicant respectfully requests allowance of claims 16-24.

Conclusion

In view of the amendments and reasons provided above, it is believed that all pending claims (claims 1-34) are in condition for allowance. Applicant respectfully requests favorable reconsideration and early allowance of claims 1-34.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicants attorney of record William P. Christie at (949) 476-0757 extension 3202.

Respectfully submitted,
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626/795-9900

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